

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois  
corporation,

Plaintiff,

v.

BANNER PHARMACAPS, INC., a Delaware  
corporation,

Defendant.

Civil Action No. 07-CV-00754-GMS

REPLY BRIEF IN SUPPORT OF ABBOTT LABORATORIES' MOTION TO DISMISS  
BANNER'S UNFAIR COMPETITION COUNTERCLAIM

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## I. SUMMARY OF THE ARGUMENT

In its opening brief, Abbott established, with ample case support, that a claim for unfair competition has three required elements, none of which has been (or could be) properly pled by Banner. (*See* Brief in Support of Abbott Laboratories' Motion to Dismiss Banner's Unfair Competition Counterclaim ("Abbott Op. Br.") (D.I. 12) at 6-11.) Banner's Brief in Opposition to Abbott Laboratories' Motion to Dismiss ("Opposition") fails to address any of these defects, further confirming that its counterclaim should be dismissed with prejudice. As discussed below, the few arguments Banner does offer – including the suggestion of a conflict-of-law issue where none exists and the belated effort to recast its counterclaim as one for tortious interference with a contract, or perhaps even an antitrust claim – should not detain the Court.

## II. SUPPLEMENTAL STATEMENT OF FACTS

Abbott supplements its opening statement of facts as follows: Banner's Paragraph IV letter to Abbott attached an "Offer of Confidential Access" ("OCA"), which stated that Banner would provide access to its "NDA, and related Drug Master File established at FDA" in order for Abbott to evaluate a possible claim of infringement. (*See* Ex. A (Offer of Confidential Access) at § 1(a).) The OCA provided that access to the NDA would be afforded to Abbott's outside counsel, up to five in-house counsel, and Abbott's independent consultants. (*Id.* at § 2(b).) Finally, the OCA permitted these individuals to copy Information "as is reasonably necessary to accomplish the purpose of this Agreement." (*Id.* at § 2(e).) When Abbott contacted Banner to request access to the NDA under the terms of the OCA, however, Banner reneged.

To enable Abbott to evaluate whether Banner's product infringed, Abbott requested that Banner provide Abbott with four categories of information:

1. The Chemistry Manufacturing and Controls ["CMC"] section of the [ ]NDA, and any other portions sufficient to show the precise

details about the proposed formulation, manufacturing instructions, batch records, and composition statements.

2. The proposed labeling and package insert.
3. Any information describing the physical, chemical, or structural properties of the active ingredient, including any statements regarding whether the active ingredient is an oligomer.
4. Any comparisons in the NDA of Banner's proposed product to Depakote, other than the actual [bioavailability]/[bioequivalence] studies[.]

(Ex. B (Emails among counsel) at 2.) Banner refused – despite its OCA's sweeping definition of "Information." (See Ex. A at § 1(a).) Instead, on October 29, 2007, Banner's counsel sent an email to Abbott's counsel making clear that Banner would only permit access to a limited portion of the NDA, and that – even to see this limited selection – Abbott would be required to fly to Banner's headquarters in North Carolina. (See Opposition (D.I. 15), Ex. 1-E.) Under this revised "offer," and quite contrary to the original OCA, no provision was made for Abbott to make copies of the NDA for analysis by its expert consultants.

### III. ARGUMENT

#### A. As A Matter Of Law, Abbott Had An Objectively Reasonable Basis To File Suit Against Banner.

The gravamen of Banner's unfair competition claim is the argument that Abbott "lacks . . . a bona fide, objectively reasonable and good faith basis to allege infringement."

(Counterclaims (D.I. 7) ¶17.) This conclusory legal assertion is not the type of well-pleaded factual allegation that this Court must credit when deciding a motion to dismiss. See *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 613 (D.N.J. 2000) ("To survive this motion to dismiss, the counter-claimants must have set forth sufficient information for one to infer that their allegations are supportable; they may not rely on bald assertions or legal conclusions made in the guise of factual allegations."). More importantly, Banner is wrong as a

matter of both law and fact. *See Neitzke v. Williams*, 490 U.S. 319, 326 (1989) (a court should dismiss a claim where it is invalid as a matter of law).

**1. Under The Hatch-Waxman Act, Abbott Was Not Required To Review Banner's NDA Before Filing A Suit For Patent Infringement.**

Contrary to Banner's unsupported assertion, Abbott was not required to obtain and review Banner's NDA before filing suit (something that Banner effectively precluded in any event). It is undisputed that Banner submitted an NDA containing a Paragraph IV certification, asserting that its product should be approved prior to the expiry of two patents owned by Abbott. It is also undisputed that this submission was an act of infringement under the Hatch-Waxman Act, sufficient by itself to justify this lawsuit. *See* 21 U.S.C. § 355(b)(2); 35 U.S.C. § 271(e)(2); *cf. Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) ("The very act of submitting an ANDA [with a Paragraph IV certification] is an act of infringement.")<sup>1</sup> Indeed, this Court has faced this issue before and has confirmed (consistent with Federal Circuit precedent) that a patent holder presented with a Paragraph IV certification notice has a right to file suit even without first reviewing the generic's application. *See Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 429 (D. Del. 2007) (Sleet, J.) (Merck sued Apotex based solely on receipt of Apotex's Paragraph IV certification letter, without first reviewing the ANDA; the Court noted that Apotex's filing of an ANDA with a Paragraph IV certification was, by statute, an act of infringement, and "[t]he statutory provisions that allow suit under these circumstances render the patentee's subjective motivations for filing suit irrelevant").

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<sup>1</sup> In this respect, the Act treats patentees (who wish to file suits for patent infringement) and generics (who wish to file suits seeking declaratory judgments of non-infringement) quite differently. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) (a prerequisite for filing a declaratory judgment suit with regards to a patent for which an applicant has filed a Paragraph IV certification is that the applicant provide the patentee with an offer of confidential access to the application). So, while Banner must *make* a qualifying offer of confidential access under the Act in order to sue Abbott, Abbott need not accept Banner's offer of confidential access to sue Banner. *See id.*

Faced with this clear precedent, Banner does not, and cannot, dispute that its filing of an NDA under 21 U.S.C. § 355(b)(2) with a request that the FDA approve its product before the expiration of the Patents is an act of infringement that “establish[es] jurisdiction by the Courts.” (Opposition (D.I. 15) at 16); *see also* 35 U.S.C. § 271(e)(2). Yet, Banner argues that its counterclaim should survive dismissal because “[a] key pleaded fact is that Abbott knew that Banner did not infringe.” (Opposition (D.I. 15) at 8.) This is wrong for several reasons.

*First*, Banner’s counterclaims nowhere allege that Abbott knew that Banner did not infringe. (*See generally* Counterclaims (D.I. 7).) Banner cannot replead its counterclaim in the text of its Opposition. At most, Banner alleges that it does not infringe Abbott’s patents (*id.* at ¶¶11 & 12), but this is a legal conclusion – indeed, the ultimate legal conclusion in this case – and this Court need not credit it in considering this motion to dismiss. *See Digene Corp. v. Ventana Med. Sys., Inc.*, 511 F.Supp.2d 407, 410 (D. Del. 2007) (in evaluating a motion to dismiss, a court “will not accept unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegation”).

*Second*, contrary to Banner’s apparent assumption, Abbott was not required to simply take Banner’s word that its product would not infringe the Patents. (*See* Opposition (D.I. 15) at 9.) This Court has made clear that a patentee cannot be put in the position of either crediting a potential infringer’s self-serving statements regarding infringement or risking liability for unfair competition if it chooses to enforce its patent rights by filing suit. *Cf. ISCO Int’l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 505-06 (D. Del. 2003) (Sleet, J.) (“If a pleading alleging inequitable conduct before the PTO were sufficient to impute knowledge of unenforceability and bad faith to the patentee plaintiff, nearly every patent infringement plaintiff would summarily be found liable for unfair competition, as the affirmative defense of inequitable conduct is routinely

asserted.”); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (the court can “dismiss antitrust allegations that require irrational inferences”).

As this Court previously explained, if an argument like Banner’s were true, “[u]nfair competition counterclaims, and in particular the element of bad faith, would be stripped of any meaning.” *ISCO*, 279 F. Supp. 2d at 506. This concern is even more acute in the context of cases, like this one, arising under the Hatch-Waxman Act. These cases all begin with a Paragraph IV certification, in which the generic applicant asserts that its proposed generic product will not infringe the innovator’s patents and/or that such patents are invalid. *See* 21 U.S.C. § 355(b)(2)(iv) (relating to NDAs); *cf.* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a similar provision for ANDAs). If Banner’s view of the law were correct, then any patent holder who receives notice of a Paragraph IV certification and files suit (as the statute clearly contemplates will happen) will be liable for unfair competition. There simply is no support in the statute for Banner’s claim that a patent holder’s right to enforce its patent rights is conditioned on its acceptance of liability for unfair competition.

## **2. Banner’s Actions Belied Its Assertion Of Non-Infringement, Giving Abbott Ample Basis To File Suit.**

As discussed above, Banner’s submission of the NDA with a Paragraph IV certification was, by itself, an act of infringement sufficient to justify this lawsuit and to undermine any claim of unfair competition. Although the Court need go no further to grant Abbott’s motion to dismiss, the objective facts lend yet more support – making clear that Abbott had well more than a reasonable basis to file this lawsuit.

Banner calls its proposed generic product “valproic acid delayed release capsules.” (Counterclaim (D.I. 7) ¶ 9.) Yet, when it came time to advise FDA of the proper reference-listed

drug for its product, Banner chose Abbott's Depakote<sup>®</sup>, not one of the many approved products containing valproic acid as the active ingredient. (*Id.*; *see also* Complaint (D.I. 1) ¶15.)<sup>2</sup>

As Banner well knows, the active pharmaceutical ingredient in Depakote<sup>®</sup> is *not* valproic acid; it is divalproex sodium – a separate chemical entity that is covered by the Patents. (Counterclaims (D.I. 7) at ¶7.) Yet, by referencing Depakote<sup>®</sup>, Banner has averred to FDA that its proposed generic product is so similar to Depakote<sup>®</sup> (and thus to Abbott's patented divalproex sodium) that FDA should rely upon all of the clinical data Abbott gathered to prove the safety and effectiveness of Depakote<sup>®</sup> in determining whether to approve Banner's product. Banner's selection of Depakote<sup>®</sup> (divalproex sodium) as the reference-listed drug for its product thus undermines the statement in Banner's Paragraph IV certification that the product contains only valproic acid, and thus would not infringe the Patents.<sup>3</sup> In light of this inconsistency, Abbott certainly was not required to trust Banner's self-serving assertions of non-infringement. Instead, Abbott was well within its rights to protect its Patents by filing this suit.

### **3. In Any Event, Banner Failed To Provide Abbott With Reasonable Pre-Suit Access To Its NDA.**

Finally, Banner ought not be heard to complain of unfair competition when it was Banner's own conduct that brought about this action. As described above, Banner could have selected an approved valproic acid product as the reference-listed drug for its proposed generic product. It did not do so. Instead, it elected to reference Abbott's Depakote<sup>®</sup> and to submit a

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<sup>2</sup> Banner's business partner, Noven, even stated that final approval of Banner's proposed product "is subject to the expiration of any applicable exclusivity periods benefiting Depakote<sup>®</sup>." (Complaint (D.I. 1), Ex. C; *see also id.* ¶16.)

<sup>3</sup> Abbott has faced this situation before. Years ago, Abbott received notice that a generic manufacturer was seeking FDA approval for a § 505(b)(2) NDA that relied on Abbott's safety and efficacy studies conducted on Depakote<sup>®</sup>, despite the fact that the NDA sought approval for a product whose active pharmaceutical ingredient allegedly was sodium valproate, not divalproex sodium. (*See* Ex. C (Citizen Petition).) Abbott sued the generic for patent infringement on the basis of its Paragraph IV certification and discovered that the generic used divalproex sodium, Abbott's patented product, in the course of manufacturing its product, thus infringing the Patents. (*See id.* at 10.) Banner may well be pursuing a similar scheme.

certification directed to Abbott's Patents covering divalproex sodium. Banner then made it effectively impossible for Abbott to review the NDA or test product samples during the short time afforded under the Hatch-Waxman Act for filing suit.

Under the Act, Abbott had only 45 days from receipt of Banner's Paragraph IV notice to file an infringement action and invoke the statutory 30-month stay on FDA approval of the NDA. *See* 21 U.S.C. § 355(c)(3)(C). The Act anticipates that a patent holder will have a reasonable opportunity to review the generic's application during that 45-day period. Applicants (at least those who wish to preserve the ability to bring an action for declaratory judgment should the innovator elect not to sue within the 45 days) are required by the statute to provide the patent holder with confidential access to the application. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc). According to the statute, this offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." 21 U.S.C. § 355(j)(5)(C)(i)(III).

In keeping with the statute, Banner included an offer of confidential access with its Paragraph IV notice, offering access to the NDA to Abbott's outside counsel, up to five in-house counsel, and any additional, independent experts or consultants retained by Abbott to review the NDA (and associated Drug Master Files). (Ex. A at § 2(b).) The OCA permitted these authorized individuals to copy the NDA materials "as is reasonably necessary to accomplish the purpose of this Agreement." (*Id.* at § 2(e).) This OCA proved wholly illusory, however.

Abbott asked Banner for access to several relevant parts of Banner's NDA, namely: (1) any portion showing "the precise details about the proposed formulation, manufacturing instructions, batch records, and composition statements[.]" including the CMC section; (2) the

“proposed labeling and package insert”; (3) “information describing the physical, chemical, or structural properties of the active ingredient, including any statements regarding whether the active ingredient is an oligomer”; and (4) “comparisons in the NDA of Banner’s proposed product to Depakote, other than the actual [bioavailability]/[bioequivalence] studies[.]” (Ex. B at 2.) Although all of this information bears directly on the issue of whether Banner’s proposed product infringes Abbott’s patents – and might explain why Banner referenced a divalproex-sodium product, rather than a valproic-acid product – Abbott never received these documents.

Instead, ignoring the terms of its OCA, Banner unilaterally decreed that “the CMC section contains the data and information that are relevant to Abbot[t]’s assessment of Banner’s Paragraph IV notice letter[.]” and refused to produce any portion of the other three categories of documents. (*See* Opposition (D.I. 15), Ex. 1-E.) Moreover, Abbott could only view this conscripted production at Banner’s headquarters in North Carolina – a restriction mentioned nowhere in the OCA. (*Id.*) So, rather than provide Abbott with access on the terms promised in the OCA, which would have complied with the statute, Banner now purported to require Abbott to accept highly-restrictive terms, demanding that Abbott’s outside and in-house counsel for Abbott (as well as independent experts) travel hundreds of miles to review a limited portion of Banner’s NDA on a single occasion. (*See id.*) Banner made no provision for any of these individuals to retain copies of the NDA for further analysis. (*See id.*) This was patently unreasonable.

**B. Because Abbott Had An Objectively Reasonable Basis To File Suit, Banner’s Second Counterclaim Fails To State A Claim.**

As discussed above, and in Abbott’s opening brief, because Abbott’s filing of this lawsuit was objectively reasonable, Banner’s unfair competition counterclaim fails to state a claim. *See* FED. R. CIV. P. 12(b)(6). Banner’s arguments to the contrary in its Opposition are unavailing.

**1. Contrary To Banner's Claims, There Is No Conflict-Of-Law Issue Here.**

Banner spends a great deal of energy arguing that Abbott has misapplied the governing law and, instead, urges that either "federal common law" of unfair competition or North Carolina law on the subject should apply. (*See* Opposition (D.I. 15) at 4-7.) This argument is misplaced.

*First*, Banner never suggests that there is any conflict amongst the alleged federal common law, North Carolina law, or Delaware law regarding unfair competition. As such, Banner manufactures a conflict where none exists.

*Second*, and contrary to Banner's assertions, there appears to be no "federal common law" of unfair competition. All three cases Banner cites in support of its "federal common law" argument applied state law regarding unfair competition and related torts. *See SmithKline*, 383 F. Supp. 2d at 703 (applying Pennsylvania law of tortious interference); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 433 (D. Del. 2006) (discussing Delaware law of tortious interference); *Zenith Labs., Inc. v. Abbott Labs.*, 1996 WL 33344963, at \*5-6 (D.N.J. Aug. 7, 1996) (applying New Jersey law).<sup>4</sup>

*Finally*, Banner's cited authority confirms that North Carolina, like Delaware, will not impose liability for unfair competition where the action at issue was explicitly authorized. *See Richardson v. Bank of Am., N.A.*, 643 S.E.2d 410, 417-18 (N.C. App. Ct. 2007) (holding that the sale of a particular type of credit insurance was not an unfair trade practice because the sale of such insurance was explicitly permitted by the state Department of Insurance, and the financing of such insurance was further regulated by statute). And *Richardson* further confirms that the issue of whether a particular action – like the filing of this complaint – is actionable in unfair

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<sup>4</sup> *SmithKline* and *Teva* also applied federal statutes and case law regarding separate antitrust claims brought in those cases.

competition is “a question of law for the court.” *Id.* at 416. Thus, under either North Carolina or Delaware law, Banner’s counterclaim should be dismissed.

**2. Regardless Which Legal Theory Is Applied, Banner’s Counterclaim Should Be Dismissed.**

In its opposition, rather than respond to Abbott’s legal arguments, Banner appears to claim that Abbott has misunderstood its skeletal counterclaim. Banner suggests that its counterclaim is some sort of umbrella claim alleging tortious interference with a contractual relationship (or a prospective business advantage), unfair competition, or possibly even an antitrust violation. (*See* Opposition (D.I. 15) at 10-16.) Of course, Banner chose to cast its own counterclaim as one for “unfair competition.” Regardless, the four scant paragraphs that comprise Banner’s counterclaim fail to state a claim under any of these theories. This counterclaim must be dismissed.

**(a) Banner’s Counterclaim Fails To State A Claim Sounding In Tort.**

The elements of a claim for tortious interference with a prospective business advantage are very similar to the elements of a claim for unfair competition under Delaware law. Tortious interference with a prospective business opportunity requires: “(a) the reasonable probability of a business opportunity; (b) the intentional interference by defendant with that opportunity; (c) proximate causation; and (d) damages, all of which must be considered in light of a defendant’s privilege to compete or protect his business interests in a fair and lawful manner.” *TruePosition, Inc. v. Allen Telecom, Inc.*, 2003 WL 151227, at \*2 (D. Del. Jan. 21, 2003) (Sleet, J.) (quoting *DeBonaventura v. Nationwide Mut. Ins. Co.*, 419 A.2d 942, 947 (Del. Ch. 1980)).

Thus, the same analysis that undermines Banner’s unfair competition counterclaim also dooms any purported claim for this tort: Banner has failed to allege a *prospective* business relationship with a third party, or that Abbott’s actions caused Banner damages in connection

with that opportunity.<sup>5</sup> *See id.*; *see also* (Abbott Op. Br. (D.I. 12) at 7-11). Furthermore, as this Court explained in *TruePosition*, “[n]ormally, lawful actions cannot form the basis of a claim of tortious interference, particularly in light of [a party]’s ‘privilege to compete and protect its own business interests.’” *See* 2003 WL 151227, at \*2. Banner’s own authority confirms this fact: “Only wrongful interferences will satisfy the tort, as some interferences are seen as justified or privileged under the aegis of competition.” *IBM v. Comdisco, Inc.*, 1993 Del. Super. LEXIS 183, at \*64 (Del. Super. Ct. June 30, 1993) (attached as Exhibit 4 to Banner’s Opposition). As such, Abbott’s filing a statutorily-authorized lawsuit against Banner cannot provide the basis for a claim of tortious interference with a prospective business advantage.

Similarly, Banner’s counterclaim fails to state a claim for tortious interference with a contractual relationship. *Edix Media Group, Inc. v. Mahani* – a case cited by Banner – explains that this tort requires (1) the existence of a contract between plaintiff and a third party; (2) defendant knew of that contract; (3) defendant’s intentional actions played a significant role in causing the breach of such contract; (4) defendant acted without justification; and (5) the breach caused injury. *See* 2006 Del. Ch. LEXIS 207, at \*46 (Del. Ch. Dec. 12, 2006) (attached as Exhibit 3 to Banner’s Opposition). Banner’s counterclaim fails to allege elements (1), (2), (3), and (5). *See TruePosition*, 2003 WL 151227, at \*2 (“Without a breach, there is no viable tortious interference claim. As to this point, Delaware law is well-settled.”) (collecting cases). As such, this legal theory, too, does not support Banner’s counterclaim.

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<sup>5</sup> Banner’s claim that its relationship with its business partner, Noven, is sufficient on this point is wrong. The tort plainly alleges a *prospective* business relationship that was damaged after the tortfeasor’s action. A pre-existing business relationship could not satisfy this element. *See TruePosition*, 2003 WL 151227, at \* 2 (a “completed and continuing contract” is not an “expected business opportunity” for the purpose of the tort where the contract in question was “consummated before the allegedly tortious conduct”).

**(b) Banner's Sham Litigation Arguments In Its Opposition Are Irrelevant And Without Merit.**

Banner also cites cases dealing with “sham litigation” and violations of the Sherman Act. (See Opposition (D.I. 15) at 10-11.) The antitrust laws, of course, have nothing to do with Banner’s unfair competition counterclaim, which never mentions the word “antitrust” and cannot in even the most charitable sense be read to state an antitrust claim. Even if Banner were attempting to allege an antitrust violation by Abbott, moreover, such a claim would fall flat as a matter of law.

First, Abbott’s filing this lawsuit is immunized from antitrust liability under the *Noerr-Pennington* doctrine. See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) (hereinafter “*PRE*”); see also *Merck*, 488 F. Supp. 2d at 429 (“Any adverse effects within the scope of a patent or statutory right to exclude, however, cannot be redressed by antitrust law.”). Because Banner failed to allege that Abbott’s “suit was both objectively baseless and subjectively motivated by a desire to impose collateral, anti-competitive injury[,]” Banner cannot argue that the narrow “sham litigation” exception to this doctrine applies here. See *id.* Furthermore, as discussed above, Abbott had strong legal and factual bases supporting its decision to sue Banner, eliminating any possible assertion that Abbott’s lawsuit is objectively baseless. (See discussion, *supra*, at Section III.A.) And it is black-letter law that the second, subjective prong of the antitrust inquiry is “irrelevant unless the litigation is objectively unreasonable.” *PRE*, 508 U.S. at 62.<sup>6</sup>

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<sup>6</sup> In any case, it is by no means clear that Banner has sufficiently alleged that Abbott’s filing this suit satisfies the subjective prong of the *PRE* test, as mere knowledge that the filing of a suit may collaterally damage a litigant is not evidence of a bad faith motive. See *PRE*, 508 U.S. at 69; see also *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1365 (S.D. Fla. 2004) (“Abbott had the legal right to file suit, and proper exercise of a legal right does not provide evidence of bad faith”).

*Second*, none of the cases cited by Banner stand for the proposition that a brand-name manufacturer's actions in suing a generic based on a Paragraph IV certification – without more – constitute sham litigation under the antitrust laws. The generic in *Zenith* alleged that plaintiff also improperly listed certain patents in the Orange Book, an allegation that was neither made nor could be made here. *See Zenith*, 1996 WL 33344963, at \*3. Similarly, in *Teva*, a generic claimed that, in addition to suing generics, plaintiffs serially changed the formulations for their branded products, filed new NDAs in support of these changed formulations, and removed the old formulations from the market to delay generic entry. *See Teva*, 432 F. Supp. 2d at 420-23. Finally, in *SmithKline*, the bases for the antitrust counterclaim was the brand-name manufacturers' allegedly fraudulent or improper procurement of invalid patents, listing those patents in the Orange Book, and then suing generic companies, as well as entering into certain settlements resolving other patent litigation. *See SmithKline*, 383 F. Supp. 2d 686, 699. No similar allegations were made by Banner here.

*Finally*, if Banner truly intended to state an antitrust claim – and it has failed to do so, for the reasons stated above – *Noerr-Pennington* immunity would also apply to bar Banner's related state law claims based on these same allegations. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 128-29 (3d Cir. 1999) (court barred state law claims for tortious interference with contract, tortious interference with prospective economic advantage, and unfair competition under *Noerr-Pennington*, finding “no persuasive reason why these state tort claims, based on the same petitioning activity as the federal claims, would not be barred by the *Noerr-Pennington* doctrine”); *see also Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 324 (D. Del. 2004) (“Because the principles of *PRE* are based on a First Amendment right of petition, those principles also apply to Universal's state law theories.”); *Salem Church (Del.)*

*Assocs. v. New Castle Cty.*, 2006 WL 2873745, at \*13 n. 116 (Del. Ch. Oct. 6, 2006) (applying the *Noerr-Pennington* doctrine to immunize the County's actions in lobbying for enactment of a bill over plaintiff's objection that no Delaware court has ever applied the doctrine, noting that plaintiff provided "no persuasive reason for the Court to ignore its principles").

Thus, regardless of the legal theory applied, Banner's second counterclaim must fail.

#### IV. CONCLUSION

For the reasons set forth above, as well as the reasons set forth in Abbott's opening brief in support of its motion to dismiss, Banner's unfair competition claim fails as a matter of law, and should be dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 12(b)(6).

Dated: March 20, 2008

Respectfully submitted,

CONNOLLY BOVE LODGE & HUTZ LLP

Of Counsel

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*Attorneys for Abbott Laboratories*

Perry C. Siatis

ABBOTT LABORATORIES

100 Abbott Park Road

Abbott Park, Illinois 60064-6034

# **Exhibit A**

**OFFER OF CONFIDENTIAL ACCESS AND CONFIDENTIALITY AGREEMENT**

OFFER OF CONFIDENTIAL ACCESS AND CONFIDENTIALITY AGREEMENT  
("Agreement"), by and between BANNER PHARMACAPS INC., a corporation having a place of business at 4125 Premier Drive, High Point, NC 27265 ("Banner") on the one hand, and ABBOTT LABORATORIES, a corporation having a place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500 ("Abbott") on the other hand, effective upon the date of a request by Abbott for access to Banner's Section 505(b)(2) New Drug Application for valproic acid 125, 250 and 500 mg delayed release capsules (Banner's NDA") filed with the U.S. Food and Drug Administration ("FDA").

**W I T N E S S E T H :**

WHEREAS, in accordance with Section 505(j)(5)(C)(i)(III) of the Federal Food, Drug, and Cosmetic Act ("the Act"), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Banner offers to make certain "Information" (as defined below) concerning Banner's NDA available to Abbott subject to the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the foregoing premises, the sufficiency of which is hereby acknowledged, and intending to be legally bound hereby, the parties agree as follows:

**1. DEFINITIONS**

- (a) "Information" means any and all information that the Providing Party (as

hereafter defined) or its representatives provides or furnishes to the Receiving Party (as hereafter defined) or its representatives, regardless of whether: (i) such Information is specifically marked or designated as “confidential” or “proprietary”, (ii) such Information is patentable, copyrightable or otherwise protected by law, or (iii) such Information is furnished verbally, in writing or in electronic form. “Information” includes, but is not limited to, any and all notes, memoranda, analyses, compilations, studies or other documents (whether in hard copy or electronic media) prepared by either party which contain or otherwise reflect such Information, and any and all copies, extracts or other reproductions of any of the same. In addition, for avoidance of doubt, “Information” includes Banner’s NDA, and related Drug Master File established at FDA.

(b) Notwithstanding the foregoing, the term “Information” does not include information that: (i) is or becomes available to the public through no wrongful act of the Receiving Party or its representatives; (ii) is known to the Receiving Party on the date of this Agreement, as evidenced by written records of the Receiving Party existing on said date; (iii) is received from a third party who has the right to disclose the same to the Receiving Party; (iv) is in the rightful possession of the Receiving Party free of any obligation of confidentiality; or (v) is independently developed by the Receiving Party without reference to, or misuse of, information furnished by the Providing Party.

(c) “Providing Party” means the party furnishing Information, and includes its subsidiary and affiliated corporations.

(d) “Receiving Party” means the party receiving Information, and includes its subsidiary and affiliated corporations.

(e) “Representatives” means any party’s employees, agents or other representatives, including advisors, attorneys, accountants, financial advisors and potential financing sources.

## **2. CONFIDENTIALITY**

(a) The parties are authorized to provide Information to each other for the sole and limited purpose of evaluating possible infringement of the patents that are the subject of Banner’s Paragraph IV certification pursuant to Section 505(b)(2)(A)(iv) of the Act in connection with Banner’s NDA (U.S. Patent Nos. 4,988,731 and 5,212,326 (“the Listed Patents”)).

(b) Persons entitled to access to the Information on the part of the Receiving Party are restricted to (i) outside counsel engaged or employed by the Receiving Party to represent them and the staff of such outside counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel, provided that such outside counsel has been identified to the Providing Party in writing; (ii) no more than five in-house counsel; and (iii) independent consultants and experts assisting in the evaluation of the Information for the Receiving Party and any employees and assistants under the control of such consultant or expert. Each such consultant and expert shall be identified by the Receiving Party to the Providing Party, and shall execute an Undertaking, in the form in Attachment A hereto, agreeing to be bound by the terms of this Agreement.

(c) Persons with access to the Information (i) shall be identified to the Providing Party before Information is provided under this Agreement; (ii) shall keep Information furnished to them by the Providing Party strictly confidential and not disclose it to other employees or agents of the Receiving Party; (iii) shall take all reasonable precautions to safeguard such Information against unauthorized disclosure; and (iv) shall not take any action inconsistent with the Providing Party’s ownership of such Information.

(d) Except to the extent required by law or judicial process and in accordance with paragraph 4 below, the Receiving Party and its Representatives shall not disclose to any third person or entity (other than those provided for in paragraph 2(b)): (i) the Providing Party's Information; (ii) the fact that such Information was disclosed to the Receiving Party; or (iii) the fact that an evaluation is taking place with respect to the Information, including the status thereof, unless exempted from one or more of these prohibitions by the express prior written consent or authorization of the Providing Party.

(e) The Receiving Party and its Representatives shall not copy, reproduce, or reduce to writing any part of the Information furnished to it by the Providing Party except as is reasonably necessary to accomplish the purpose of this Agreement. Any such copies, reproductions or reductions to writing shall become the property of the Providing Party.

(f) The Receiving Party shall be responsible for any breach of this Agreement by its officers, directors, employees or other representatives, and shall take all reasonable measures to restrain such persons from the unauthorized use or disclosure of the Information.

### **3. USE OF INFORMATION**

The Abbott and its Representatives shall use the Information provided to them solely for the limited purpose of determining whether to initiate an action against Banner for infringement of the Listed Patents.

### **4. GOVERNMENTAL REQUESTS FOR DISCLOSURE**

In the event that the Receiving Party or any of its Representatives receives a request or is required by applicable law to disclose to a court or government agency of competent jurisdiction all or any part of the Providing Party's Information, the Receiving Party or its representatives

shall promptly notify the Providing Party of the request, and shall to the extent requested, consult with and assist the Providing Party in seeking a protective order or other appropriate protective remedy. If such order or other remedy is not obtained or the Providing Party waives compliance with the terms hereof, the Receiving Party or its representatives, as the case may be, shall disclose only that portion of the Information which, in the reasonable opinion of its counsel, is legally required to be disclosed, and shall exercise their respective best efforts to assure that confidential treatment will be accorded such Information by the persons or entities receiving it. The Providing Party shall be given a reasonable opportunity to review the Information prior to its disclosure.

## **5. RETURN OF INFORMATION**

(a) If Abbott does not commence an action against Banner alleging infringement of the Listed Patents within forty-five (45) days of its receipt of Banner's notice of its Paragraph IV certification against those patents (the "45-day period") which accompanies this Offer of Confidential Access and Agreement, Abbott shall cause persons entitled to access to the Information to return immediately to Banner (a) all Information that Banner has provided under this Agreement, and (b) all non-privileged notes, analyses, studies or other documents to the extent that they contain information in Banner's NDA, and shall notify Banner that this has been done.

(b) If Abbott commences an action against Banner alleging infringement of the Listed Patents within the 45-day period:

(1) while the litigation is pending, the portions of Banner's NDA provided and all notes, analyses, studies or other documents to the extent that they contain information in the ANDA, shall be treated as information under the highest level of confidentiality under any

protective order entered in the action brought against Banner, and until such a protective order is entered subsections (2)(c)(ii)-(iv) of this Agreement continue to apply; and

(2) Abbott shall cause persons entitled to access to the Information to return the portions of Banner's NDA provided, and all notes, analyses, studies or other documents prepared to the extent that they contain information in Banner's NDA, within thirty (30) days after the final determination of the action brought against Banner.

## **6. INJUNCTIVE RELIEF**

The parties agree that money damages will not be a sufficient remedy for any breach of this Agreement by the Receiving Party or its representatives, and that the Providing Party is entitled to injunctive relief and specific performance as remedies for any such breach. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or in equity.

## **7. TERM; TERMINATION**

This Agreement shall be effective upon a request by Abbott for access to Banner's NDA, and until such time as the Information is returned pursuant to Paragraph 5 above. This Agreement may be renewed upon such terms as may be agreed upon by the parties. Upon termination of this Agreement, the Receiving Party shall fulfill its obligations to return the Providing Party's Information pursuant to above paragraph 5 of this Agreement. The Receiving Party's obligations of confidentiality pursuant to above paragraph 2 shall survive the termination of this Agreement.

## **8. SEVERABILITY**

The invalidity or unenforceability of any provision of this Agreement shall not affect the

validity or enforceability of any other provision, all of which shall remain in full force and effect.

**9. ASSIGNMENT**

This Agreement shall not be assigned without the prior written consent of the Providing Party.

**10. NOTICES**

All notices and other communications sent under any provision of this Agreement shall be addressed to Banner and Abbott at the addresses set forth below:

For Banner:

Charles L. Cain  
Global Vice President, Legal &  
Public Affairs  
Banner Pharmacaps Inc.  
4100 Mendenhall Oaks Pkwy, Suite 301  
High Point, NC 27265

For Abbott:

Name  
Title  
Address

All notices shall be in writing, and shall be effective when received.

**11. GOVERNING LAW**

This Agreement shall be construed in accordance with the laws of the State of North Carolina, without regard to conflict of laws principles.

**12. HEADINGS**

The section headings in this Agreement are for convenience only, and shall not alter or affect the meaning or interpretation of any provision of this Agreement.

**13. COUNTERPARTS**

This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same Agreement.

**14. COMMUNICATIONS**

Delivery of any counterpart signature page of this Agreement, written communication or notice hereunder by facsimile shall be equally as effective as delivery of a manually executed original of such counterpart signature page, communication or notice. Any party delivering a counterpart signature page, written communication or notice hereunder by facsimile shall also deliver a confirmatory hand-signed original.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed upon a request by Abbott for Access to Banner's NDA.

BANNER PHARMACAPS INC.

By: \_\_\_\_\_

Title: \_\_\_\_\_

ABBOTT LABORATORIES

By: \_\_\_\_\_

Title: \_\_\_\_\_

**ATTACHMENT A**

I, \_\_\_\_\_, declare and state as follows:

1. My present residential address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_, and the address of my present employer is \_\_\_\_\_.
3. My present occupation or job is \_\_\_\_\_.
4. I have received and carefully read the foregoing Offer of Confidential Access and Confidentiality Agreement, and understand its provisions.
5. In accordance with paragraphs 2(b) - 2(d) of the Agreement, I hereby undertake to abide by all provisions of the Agreement. Particularly, I undertake: (a) to hold in confidence and not to disclose any Information (as defined in paragraph 1 of the Agreement), which is provided to me by a party to the Agreement, to any individual or entity other than the persons permitted in the Agreement; (b) to use Information provided to me solely for the purpose of evaluating Information provided to me by any party; and (c) to return any Information in accordance with paragraph 5 of the Agreement.

Dated: \_\_\_\_\_

\_\_\_\_\_

Signature

# **Exhibit B**



**Jason G. Winchester/JonesDay**  
Extension 54373  
03/18/2008 12:19 PM

To craubicheck@flhlaw.com  
cc Melissa B Hirst/JonesDay@JonesDay  
bcc

Subject Fw: Offer of Confidential Access Agreement

Charlie -

To move our discussions forward on getting access to the CMC section of the NDA, I am resending to you below the few changes that Abbott proposed to the original OCA proffered by Banner in the paragraph IV notice. With these changes, Abbott would be willing to sign the OCA and take any materials Banner is willing to share pursuant to the OCA, pending entry of a protective order in the case.

In addition to the OCA, is Banner willing to provide us with a copy of its proposed labeling at this stage? Given that Banner has selected Depakote as the RLD, we believe that the product labeling Banner has submitted to FDA will likely contain relevant information. Obviously we will be seeking the labeling and all other portions of the NDA in discovery, and we believe it will speed the case along if Banner would produce this material now.

I will be tied up in depositions tomorrow and Thursday, but can make time to talk today until about 4 EST. Otherwise, I may be able to take a break tomorrow to talk if there is a convenient time for you, or perhaps we could talk after hours on Thursday. I should be cooling my jets at LaGuardia at 6 EST or so. I do not want to let me schedule delay this effort, however, so perhaps you and Melissa can talk about the OCA issues without me. JGW


Jason G. Winchester  
JONES DAY  
77 W. Wacker Dr., Suite 3500  
Chicago, IL 60601-1692  
312.269.4373 (Direct)  
312.782.8585 (Facsimile)

----- Forwarded by Jason G. Winchester/JonesDay on 03/18/2008 11:47 AM -----



**Jason G. Winchester/JonesDay**  
Extension 54373  
10/26/2007 09:06 AM

To CLCain@banpharm.com  
cc

Subject Re: Offer of Confidential Access Agreement 

Charles -

Thanks for getting back to me. Here are Abbott's proposed changes to the Offer of Confidential Access:

1. Paragraph 5(a). In the fifth line, insert "or destroy" after "Banner" and before "(a) all Information . . ." Also, at the end of subparagraph 5(a), add the following sentence: "Notwithstanding the foregoing, Abbott's outside counsel shall be permitted to retain one copy of all Information that Banner has provided under this Agreement and all associated notes, analyses, studies or other documents relating to Banner's NDA."
2. Paragraph 5(b)(2). In the first line, add "to Banner or destroy" after "return" and before "the"
3. In paragraph 10, Abbott designates Perry C. Siatis, Senior Counsel, Abbott Laboratories, 100 Abbott Park Road., Dept. 324, Bldg. AP6A, Abbott Park, IL 60064.

If these changes are acceptable, we would like to obtain relevant portions of Banner's NDA for review under the terms of the OCA. Specifically, Abbott requests:

1. The Chemistry Manufacturing and Controls section of the ANDA, and any other portions sufficient to show the precise details about the proposed formulation, manufacturing instructions, batch records, and composition statements.
2. The proposed labeling and package insert.
3. Any information describing the physical, chemical, or structural properties of the active ingredient, including any statements regarding whether the active ingredient is an oligomer.
4. Any comparisons in the NDA of Banner's proposed product to Depakote, other than the actual BA/BE studies, which we are not asking for at this time.

I am available today to discuss any of these issues. Thanks. JGW

Jason G. Winchester  
Jones Day  
77 W. Wacker Dr., Suite 3500  
Chicago, Illinois 60601-1692  
312.269.4373 (direct)  
312.782.3939 (main)  
312.782.8585 (fax)  
CLCain@banpharm.com



**CLCain@banpharm.com**

10/26/2007 07:44 AM

To jgwinchester@jonesday.com

cc

Subject Offer of Confidential Access Agreement

Jason,

I received your voice mail and do not anticipate a problem with your requested changes. Would you like to forward me language to address them, or would you prefer me to revise?

Charles

Charles L. Cain  
Global Vice President, Legal and Public Affairs  
Banner Pharmacaps Inc.  
4100 Mendenhall Oaks Parkway, Suite 301  
High Point, NC 27265  
336.812.7010/ Fax 336.812.7054  
clcain@banpharm.com

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# Exhibit C

# HOGAN & HARTSON

L.L.P.

6473 01 JUL 15 2004

DAVID M. FOX  
PARTNER  
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July 15, 2004

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## BY HAND DELIVERY

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

## CITIZEN PETITION

On behalf of Abbott Laboratories ("Abbott"), this citizen petition is submitted under section 505 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 CFR 10.30, and other provisions of law.

This petition requests that the Commissioner of Food and Drugs (the "Commissioner") refrain from approving certain applications submitted under section 505(b)(2) of the FDCA that reference Depakote® (divalproex sodium delayed-release tablets), but which contain a different active ingredient than that contained in Depakote®. The approval of any such application, where the sponsor relies on the prior approval of Depakote® to establish the safety and effectiveness of the proposed product, would be arbitrary, capricious, and contrary to law. The Food and Drug Administration ("FDA") recently granted tentative approval to one such application, submitted by Andrx Laboratories ("Andrx"), which appears to lack the data necessary to support approval under section 505(c) of the FDCA.

The Andrx 505(b)(2) application also raises unresolved procedural and policy issues regarding the appropriate scope of section 505(b)(2). In its landmark citizen petition response regarding the scope of section 505(b)(2), FDA called into question the appropriateness of using section 505(b)(2) "to obtain approval of drug products for which the *only* difference from the listed drug is in the form of the active ingredient, such as a change in salt." FDA Consolidated Petition Response, Docket Nos. 2001P-0323, 2002P-0447, and 2003P-0408 (Oct. 14, 2003) at 34 (emphasis in original) ("Consolidated Petition Response"). The agency concluded that such applications "may have undesirable policy and public health consequences." *Id.* Accordingly, FDA stated that it "is considering whether to begin

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a public process” and would reserve the issue “for further review” to determine whether “there is some narrow subset of applications that should be exempted from the scope of section 505(b)(2) in the future.” *Id.*

The Andrx 505(b)(2) application falls squarely within FDA’s stated concerns; the only proposed difference from the reference drug is in the active ingredient. *See id.* The agency, however, has yet to initiate the public process outlined in its Consolidated Petition Response. FDA has not indicated how it intends to resolve the public policy and public health issues presented by the Andrx 505(b)(2) application. Therefore, Abbott respectfully requests that the Commissioner withhold final action on the Andrx application, and any similarly situated applications, pending resolution of the scientific, legal, and policy issues associated with such applications.

### ACTIONS REQUESTED

Abbott respectfully requests that the Commissioner: (1) Refrain from granting final approval to the Andrx 505(b)(2) application and any similarly situated applications; and (2) initiate the public process previously announced by FDA, to seek input from interested persons, including industry and consumer groups, on the use of section 505(b)(2) to obtain approval of drug products for which the *only* proposed difference from the reference drug is the active ingredient.

### STATEMENT OF GROUNDS

#### I. BACKGROUND

Depakote® Delayed-Release Tablets (“Depakote®”) contain the active ingredient divalproex sodium. FDA first approved Depakote® in 1983 for the treatment of absence epilepsy. In the mid-1990s, after review of extensive clinical data, FDA approved Depakote® for use in the treatment of complex partial seizures and the manic phases of bipolar disorder, and in the prophylaxis of migraine headaches. Depakote® is marketed in 125, 250, and 500 mg strengths.

In December 1999, Andrx submitted to FDA an abbreviated new drug application (“ANDA”) that referenced Depakote®.<sup>1/</sup> Andrx’s ANDA, however,

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<sup>1/</sup> An ANDA is approved by FDA under section 505(j) of the FDCA, which permits applicants to rely exclusively on the clinical investigations conducted on a previously approved “listed” drug. *See* 21 USC 355(j). Among other things, an ANDA applicant must demonstrate that the active ingredient in its proposed product is “the same as that of the listed drug.” *Id.* at 355(j)(2)(A)(ii).

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described a product that, according to the company, did not contain divalproex sodium. See Tab 1, Notice of Certification of Invalidity or Noninfringement of a Patent (received Mar. 6, 2000) at 2.2/ Rather, Andrx stated that its product contained "sodium valproate" in a delayed-release tablet dosage form. Valproate sodium is a salt form of valproic acid; it is distinct from divalproex sodium, the active ingredient in Depakote®.<sup>3/</sup>

On January 24, 2001, FDA notified Andrx that the agency was suspending further review of Andrx's application because the proposed product did not meet the statutory requirements for an ANDA. See Tab 2 at 2. After further argument by Andrx, the agency rejected the ANDA on the ground that Andrx's product contains a different active ingredient than that in the reference drug, Depakote®. Specifically, the agency stated:

[T]he ANDA cannot be approved under Section 505(j) of the Act because the active ingredient in the proposed product, i.e., valproate sodium, as determined by [the Office of Generic Drugs ("OGD")] during the ANDA review is not the same as the active ingredient in the RLD, i.e., divalproex sodium.

Tab 2, Exhibit B, Letter from Gary J. Buehler to Andrx (July 18, 2002).<sup>4/</sup>

Shortly thereafter, Andrx contacted FDA to inquire about submitting another application for the same product rejected under section 505(j). See Tab 2, Exhibit C, Letter from Andrx to Russell G. Katz, M.D. (Aug. 29, 2002). Importantly,

---

<sup>2/</sup> Much of the information concerning Andrx's applications and communications with FDA is based on documents released in patent infringement litigation brought by Abbott against Andrx. See Tab 2, Joint Status Report and Motion to Extend Stay, *Abbott Labs. v. Andrx Corp.*, Case No. 00-7823-CIV-HIGHSMITH/GARBER (S.D. Fla. Oct. 8, 2002) (unsealed Dec. 4, 2003). The Joint Status Report and each of the exhibits, including those marked "CONFIDENTIAL," were unsealed by the court and are now available as public documents.

<sup>3/</sup> Andrx states that its product contains a different active ingredient than divalproex sodium. The basis for Abbott's patent litigation is that the Andrx product contains some divalproex sodium.

<sup>4/</sup> Valproate sodium, which Andrx claims is the active ingredient in its product, is the active ingredient in Abbott's product, Depacon® (valproate sodium) Injection. Depacon® is not available in a tablet dosage form. Also, Depacon® is approved for use only in treating absence epilepsy and complex partial seizures; Depakote®, by contrast, also is approved for use in treating bipolar disorder and in preventing migraine headaches.

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Andrx suggested that it would seek to submit an application under section 505(b)(2) with the same substantive data as that submitted in its erstwhile ANDA. *See id.* When Andrx provided Abbott with written notification of the filing of its 505(b)(2) application, the company used the same patent notification form that it used in support of its ANDA. *Compare* Tab 3, Notice of Certification of Invalidity or Noninfringement of a Patent (received Mar. 27, 2003) *with* Tab 1. Andrx even neglected to revise the title of its second patent notification. The second notification cites 21 CFR 314.94 and 314.95, which apply to ANDAs; it should have cited 21 CFR 314.50 and 314.52, which apply to 505(b)(2) applications.<sup>5/</sup> Andrx essentially repackaged its rejected ANDA into a substantively identical 505(b)(2) submission.

On January 14, 2004, Andrx announced that FDA had issued an “approvable letter” for Andrx’s 505(b)(2) application. Tab 4, Andrx Press Release. Andrx further stated that the company intends to “compete in the same market as the Depakote® family of brand products” and will market its product for the same approved uses as Depakote®, *i.e.*, “for the treatment of manic episodes associated with bipolar disorder, various seizure disorders and prophylaxis of migraine headaches.” *Id.*

Finally, on May 10, 2004, Andrx announced that FDA had issued a tentative approval of its 505(b)(2) application. *See* Tab 5, Andrx Press Release. The press release confirms that the Andrx product will have the same dosage form (delayed-release tablets) and same strengths as Depakote®, and will be used for the same indications (mania, epilepsy, and migraine headaches). *See id.*

## II. ARGUMENT

As explained below, the agency must refrain from approving the Andrx 505(b)(2) application. The application fails to meet the requirements of section 505(b)(2), as interpreted by the agency. It also raises the precise public policy and public health considerations identified by FDA in its Consolidated Petition Response. In all, the Andrx 505(b)(2) application is contrary to the agency’s carefully structured legal and policy framework.

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<sup>5/</sup> Abbott filed a second patent infringement suit in the Southern District of Florida based on the Andrx 505(b)(2) application. The previous lawsuit involving the ANDA was dismissed. *See Abbott Labs. v. Andrx Corp.*, Case No. 03-60867 (S.D. Fla. filed May 2003). The filing of this second lawsuit triggered a stay on FDA’s authority to grant final approval to Andrx’s 505(b)(2) application. *See* 21 USC 355(c)(3)(C).

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**A. The Andrx 505(b)(2) Application Cannot be Approved on the Basis of a Prior Finding of Safety and Effectiveness for Depakote®**

Section 505(b)(2) of the FDCA permits the filing of a new drug application (“NDA”) where the sponsor does not have a right of reference to all of the studies needed to support approval. *See* 21 USC 355(b)(2). As interpreted by FDA, section 505(b)(2) provides an alternative to section 505(j), where new studies are needed to support a proposed change to a listed drug product. *See* Consolidated Petition Response at 9. In FDA’s words:

(1) if a proposed modification may be approved without additional studies, the drug may be reviewed in a 505(j) application that relies *entirely* on the Agency’s finding of safety and effectiveness for the listed drug; and (2) if the proposed modification will require additional data for approval, the drug may be reviewed in a 505(b)(2) application that relies *in part* on the Agency’s finding of safety and effectiveness for the listed drug.

*Id.* (emphasis in original). In the latter case, under section 505(b)(2), “[t]he safety and effectiveness of any differences between the listed drug and the drug proposed in the 505(b)(2) application *must be supported by additional data, including clinical or animal data, as appropriate* (citation omitted).” *Id.* at 14 (emphasis added). Were no additional data necessary, the product could be reviewed and approved under section 505(j).

This distinction between section 505(b)(2) and 505(j) – as drawn by the agency – points out a fundamental flaw in the Andrx 505(b)(2) application. By all appearances, Andrx’s 505(b)(2) application is simply a carbon copy of its ANDA – no more and no less. Andrx does not appear to have submitted any additional data to support a fundamental change to the active ingredient in the reference drug, Depakote®. That is, the Andrx product purports to use the valproate sodium salt of valproic acid, which is distinct from the form of the active ingredient (divalproex sodium) contained in Depakote®. The agency determined that this departure from the reference drug rendered the Andrx application unreviewable under section 505(j). Yet, by all appearances, Andrx simply resubmitted its ANDA as a 505(b)(2) application. Such an approach is fundamentally at odds with the statutory framework presented in the Consolidated Petition Response.

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Andrx must – as a matter of science and law – submit additional data to support its change to the reference drug. As FDA stated in its Consolidated Petition Response, the precise quantity and quality of data needed to support the change “will vary from case to case.” *Id.* at 14. What is clear, however, is that a 505(b)(2) application must be supported by data different from and *in addition to* any data that FDA is permitted to review under section 505(j).<sup>6/</sup> At a minimum, and to remain consistent with FDA’s interpretation of the law, Andrx must support its change to the reference drug with data beyond that required for an ANDA.

This conclusion is confirmed by the express provisions in section 505(j) regarding authorized changes to listed drug products. Under section 505(j)(2)(C), a sponsor may seek to submit an ANDA for a pharmaceutical alternative product, including a product with a different strength or dosage form from that of the reference drug. *See* 21 USC 355(j)(2)(C). Permission may be granted if FDA determines that no clinical investigations would be needed to demonstrate the safety and effectiveness of the product. *See* 21 CFR 314.93(e). The one change that is not permitted, however, is a change to the active ingredient in a single ingredient drug product. *See* 21 USC 355(j)(2)(A)(ii). This statutory prohibition reflects a fundamental determination: A change to the active ingredient will always require reference to additional clinical data that cannot be reviewed under section 505(j), but which are essential to the safety and effectiveness of the product.

In sum, Andrx cannot ignore those requirements of section 505(j) that it cannot meet, yet gain approval of the same product, with the same application and data, under section 505(b)(2). To find otherwise would be to elevate form over substance and negate the important statutory and scientific distinctions drawn by the agency between sections 505(b)(2) and 505(j).

#### **B. Andrx Must Resubmit its Proposed Product under the ANDA Suitability Petition Process**

As explained above, the Andrx 505(b)(2) application plainly conflicts with the regulatory framework outlined by the agency in its Consolidated Petition Response. There is, however, a regulatory pathway readily available to Andrx that is consistent with FDA’s regulatory construction of section 505(b)(2).

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<sup>6/</sup> In addition to *in vivo* bioequivalence studies, FDA has long held that it may also review the results of “limited confirmatory testing” under section 505(j). *See* 57 FR 17950, 17958 (Apr. 28, 1992); 54 FR 28872, 28880 (July 10, 1989).

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The agency has determined that the active ingredient in Andrx's proposed product is valproate sodium. *See* Tab 2, Exhibit B. Valproate sodium is the active ingredient in the approved drug product known as Depacon® Injection. Andrx could avoid the conflict identified above by referencing Depacon® and submitting data sufficient to support a change from an injectable dosage form to a delayed-release tablet dosage form. That is, Andrx could apply under the "suitability petition" process for a change from an injectable to a tablet dosage form. *See* 21 USC 355(j)(2)(C); 21 CFR 314.93. The "suitability petition" process allows an applicant to pursue an ANDA, despite a difference in dosage form, if it can demonstrate that no additional investigations are needed to demonstrate the safety and effectiveness of the proposed product. *See id.* If the petition were granted, Andrx could proceed under section 505(j) to gain approval of a pharmaceutical alternative to Depacon®. *See* 21 CFR 314.93(c). If the petition were denied, Andrx could proceed under section 505(b)(2), and would use the 505(b)(2) process to submit whatever additional clinical and other data FDA determined is needed to assure the safety and effectiveness of the tablet dosage form.

This approach not only resolves the conflict, it is consistent with FDA's interpretation of the regulatory role of section 505(b)(2). As the agency explained in the Consolidated Petition Response:

Thus, Congress created a new type of application, a 505(b)(2) application to fill specific gaps left by the other approval pathways: a 505(b)(2) application can be used for approval of those changes that are not so significant that they require a stand alone NDA, but that are significant enough that they may require additional safety or effectiveness data (and, therefore, are not eligible for approval under section 505(j)).

Consolidated Petition Response at 16. Moreover, the suitability petition process would provide the opportunity for the agency and all interested persons to consider whether the change proposed by Andrx, from an injectable to a tablet dosage form, requires the submission of data under section 505(b)(2).

Andrx circumvented this process by referencing Depakote® rather than Depacon® and styling its application as an ANDA with a different form of the active ingredient. When FDA determined that this was improper, Andrx sought to remedy the problem by simply resubmitting its application under section 505(b)(2). Andrx, however, never addressed the fundamental issue, namely, that a change in the active ingredient from that of the listed drug requires an additional showing of

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safety and effectiveness. Very clearly, Andrx must reference Depacon® and proceed under the suitability petition process, or Andrx must invest in its own clinical development program.

As FDA made clear in the Consolidated Petition Response, “[t]he linchpin of FDA’s interpretation of 505(b)(2) is that a 505(b)(2) applicant may rely on the FDA’s findings of safety and effectiveness for a listed drug *only to the same extent an ANDA applicant may rely on such findings under section 505(j).*” Consolidated Petition Response at 14 (emphasis added). Having presented a product with a different active ingredient, Andrx failed to meet the threshold for review under section 505(j). That is, Andrx was told it could not rely on FDA’s prior findings of safety and effectiveness for Depakote®. In short, and to the extent Andrx continues to reference Depakote®, the “linchpin” has been pulled from Andrx’s 505(b)(2) application.

**C. The Andrx 505(b)(2) Application Raises the Precise Policy Concerns Outlined by FDA in its Consolidated Petition Response**

In its Consolidated Petition Response, FDA made clear that it has rarely applied section 505(b)(2) to products that differ from reference drugs only in the form of the active ingredient. See Consolidated Petition Response at 33. The agency then recited several policy reasons why approval of such products was not in the public interest. Consequently, the agency said that it “may wish to consider further whether there is some narrow subset of applications that should be exempted from the scope of section 505(b)(2) in the future.” *Id.* at 34. The agency then “reserv[ed] for further review” through a “public process” resolution of the public health and policy reasons it had identified. *Id.*

Andrx’s application raises the precise concerns identified by FDA in its Consolidated Petition Response. First, approval of Andrx’s product would not result in an innovative drug product with any new therapeutic benefits. Second, approval of the product would undermine incentives for the development of new active moieties. And third, approval of the product would contribute to the proliferation of pharmaceutical alternative products, with resulting confusion in the marketplace. The Andrx 505(b)(2) application was reviewed and tentatively approved without any resolution of the issues memorialized in the Consolidated Petition Response. The public process suggested by the agency likewise has not been initiated. See Consolidated Petition Response at 34.

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1. *The Andrx product offers no new or different therapeutic effect and no improvement in safety or effectiveness*

Andrx's 505(b)(2) application will not result in bringing an improved product to market. The value of section 505(b)(2) is as a pathway for bringing to market innovative changes to already approved drug products. *See, e.g.*, Consolidated Petition Response at 15, 18-21. Indeed, the 505(b)(2) successes cited by FDA in the Consolidated Petition Response include novel treatments for exposure to radiological and chemical agents; products with specific labeling for pediatric patients; and novel combination products that bring real benefits to the public. *See id.* at 18-21. Andrx's proposed product does not provide any innovation in terms of safety or effectiveness.

2. *Approval of the Andrx product will undermine incentives for the development of new moieties*

Andrx cannot market a divalproex sodium product without infringing Abbott's patents.<sup>7/</sup> Andrx therefore is attempting to use 505(b)(2) to gain approval of a valproate sodium product, albeit with indications that are identical to those approved for Depakote®. This strategy is designed solely to undermine Abbott's intellectual property rights and its investment in extensive clinical testing in support of new uses for Depakote®.

Andrx's strategy is clear. In its most recent notification to Abbott, Andrx described the manufacturing process for its proposed product:

The initial manufacturing step for Andrx' Proposed Product, utilizing divalproex sodium, is performed *outside the United States* and outside any United States territories subject to United States patent laws. This initial formulation step involves adding excess sodium hydroxide solution to divalproex sodium, thereby resulting in a high pH solution . . . which contains non-oligomeric, non-complexed sodium valproate. . . . The sodium valproate in pH-adjusted solution is then shipped into the United States where the sodium valproate pH-

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<sup>7/</sup> *See Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002) (upholding the validity of Abbott's patents). On March 15, 2004, the District Court for the Northern District of Illinois determined, after a trial on the merits, that TorPharm's proposed generic version of Depakote® infringed Abbott's patents. *See Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043 (N.D. Ill. Mar. 15, 2004).

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adjusted solution is diluted with alcohol and sprayed onto anhydrous lactose to form a granulation.

Tab 3 at 3 (emphasis in original). Thus, Andrx's proposed product begins with divalproex sodium, Abbott's patented active ingredient. The divalproex sodium is intentionally altered overseas, outside the reach of United States patent laws, and then brought into the country to be granulated. Clearly, Andrx is trying to evade the scope of Abbott's intellectual property, rather than to bring an innovative product to market.

The agency already has determined that Andrx's proposed product does not meet the statutory requirements for approval of a generic divalproex sodium product.<sup>8/</sup> Approval of this same product (*i.e.*, valproate sodium delayed-release tablets) under 505(b)(2), based on a reference to Depakote® and based on the same substantive information that was rejected under 505(j), would disrupt the careful balance between innovator and generic rights under the Hatch-Waxman Act. *See* Consolidated Petition Response at 2. The agency's determination under section 505(j) should protect Abbott's investment in Depakote® until the expiration of its valid patents, when Andrx may then seek approval of a therapeutically equivalent divalproex sodium product.

### 3. *The Andrx product will lead to confusion in the marketplace*

The agency acknowledged when it rejected Andrx's ANDA that "a drug product containing valproate sodium will not be rated therapeutically equivalent to a drug product containing divalproex sodium, since they will not contain the same active ingredient." Tab 2, Exhibit B. In its Consolidated Petition Response, the agency recognized that the approval of such products under section 505(b)(2) may lead to inappropriate marketplace substitution and confusion, and adverse impacts on patient care. *See* Consolidated Petition Response at 33-34.

The Andrx product cannot be represented as "therapeutically equivalent" to Depakote® because Andrx states it does not contain the same active ingredient; at the same time, it cannot readily be distinguished. Andrx seeks to exacerbate this confusion by introducing its product in the same market as Depakote®. *See* Tab 4 (stating that the company intends to "compete in the same

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<sup>8/</sup> As explained above, Andrx's product purports to contain valproate sodium and should be submitted for approval based on a direct reference to Depacon®.

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market as the Depakote® family of brand products” and will market the product “for the treatment of manic episodes associated with bipolar disorder, various seizure disorders and prophylaxis of migraine headaches.”).

The company’s intent is further clarified in its correspondence with FDA. In one letter to the agency, Andrx asked whether the labeling of its proposed product would “contain the statement that the product is bioequivalent to Depakote?” Tab 2, Exhibit C. Including such a statement in the Andrx labeling would encourage inappropriate substitution and confusion. Andrx would be able, through advertising and promotion, to market its product as one that may be used in place of Depakote®, despite the fact that the product was denied approval under the agency’s generic drug program and will not receive an “AB” therapeutic equivalence rating.

### III. CONCLUSION

Final approval of the Andrx 505(b)(2) application, based on FDA’s prior finding of safety and effectiveness for Depakote®, would stand in direct conflict with the agency’s interpretation of section 505(b)(2) in the Consolidated Petition Response. Andrx must either re-cast its product as a pharmaceutical alternative to Depacon®, or invest in a clinical development program to support the approval of valproate sodium for each of the uses it seeks under its 505(b)(2) application.

Moreover, by Andrx’s own admission, the alleged differences between the active ingredient in its product and that in Depakote® offer no therapeutic benefit to the patient, but are merely an attempt to evade the scope of Abbott’s intellectual property. It therefore raises precisely the policy concerns outlined by FDA in its Consolidated Petition Response. Final approval of Andrx’s application will not bring to market any product with a new therapeutic benefit, will undermine incentives for the development of new active moieties, and will lead to confusion in the marketplace, all to the detriment of the public health.

Abbott therefore requests that FDA refrain from approving the Andrx 505(b)(2) application, and instead promptly initiate the public process described in the Consolidated Petition Response.

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### ENVIRONMENTAL IMPACT

The actions requested in this petition are subject to categorical exclusions under 21 CFR 25.30 and 25.31.

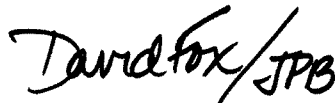
### ECONOMIC IMPACT

Information on the economic impact of this proposal will be submitted upon request of the Commissioner of Food and Drugs.

### CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink that reads "David Fox / JPB". The signature is stylized with a large, sweeping 'D' and 'F'.

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**CERTIFICATE OF SERVICE**

I hereby certify that, on March 20, 2008, a true and correct copy of the foregoing document, entitled **Reply Brief in Support of Abbott's Motion to Dismiss Banner's Unfair Competition Counterclaim**, was served on the following persons via CM/ECF filing and the following methods:

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